IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:
Yasuo SUZUKI et al.	: **Attorney Docket No. 2004_1390A**
Serial No. 10/506,469	: **Group Art Unit 1623**
Filed October 15, 2004	: **Examiner Devesh Khare**

NOVEL BRANCHED SIALO-SUGAR MOLECULES AND ANTIVIRAL AGENTS USING THE SAME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 CFR 1.132

I, Yasuo SUZUKI residing at c/o 102, 8-3, Sena 1-chome, Shizuoka-shi, Shizuoka 420-0911, Japan, declare as follows:

1. **Dr. Pharm., Shizuoka College of Pharmacy, Japan.**

   Professor at University of Shizuoka, Japan, School of Pharmaceutical Sciences, Dept. of Biochemistry (October 1, 1989 - present).

   Professor at Chubu University, Japan, College of Life and Health Sciences, Dept. of Biomedical Sciences (April 1, 2006 - present).

2. **Social Activities**

- **Vice president of The Japanese Society of Carbohydrate Research**
- **Director of the Japan Consortium for Glycobiology and Glyctechnology**
- **Adjunct Professor of Griffith University, Australia**
- **Visiting Professor of Zheijang Academy of Medical Sciences, China**
- **The Pharmaceutical Society of Japan Award '04; Chunichi Cultural Award '04**

3. **List of papers and pulications authored or co-authored by Declarant; See attached list.**

4. The named inventor of the invention described and claimed in the above-identified application, Ser. No. 10/506,469.

5. The author of Susuki reference (Prog. Lipid Res. Vol. 33, No.4, pp 429-457, 1994) and the co-author of Masuda et al reference (FEBS Letters 464, 71-74, 1999) that have been cited by the Examiner as references of the § 103 (a) rejection.

6. I have studied the above-identified application, the Office Action therein dated February 23, 2007, and the references relied upon by the Examiner in rejecting the claims.

7. With respect to the Office Action issued on the above-identified application, I have an opinion that:

First of all, it is important and consideration is respectfully required that the basic structure of the molecule of the invention is a functional glicolipid that was obtained from an allantoic membrane of embryonated hen eggs for the first time in the world as fars as I know.

According to structural analysises by the inventor, It was thought by the binding analyses of the viruses which bind to α 2-3 or 2-6 sialyl LacNAc structure that the molecule possesses a branched sugar chain structure of sialic acid (5-N-acetyl neuraminic acid: Neu5Ac) α2-3 hexose (Hex: e.g. Gal) β1-N-acetyl hexosamine (HexNAc: e.g. GlcNAc or GalNAc) and Neu5Acα2-6Hex (e.g. Gal) β1-HexNAc (e.g. GlcNAc or GalNAc) at a chain end thereof.

A notable feature of the molecular structure is that it binds to both of human influenza A, B viruses that cause epidemics among humans, and avian influenza A viruses (including Highly Pathogenic Avian Influenza, HPAI that is currently causing worldwide epidemics) that cause epidemics among avians and pig or horse influenza A viruses, and that it inhibits infection of these viruses to a host cell.

A molecule that binds to both of human influenza virus and the other animal influenza viruses (in other words, all of influenza A viruses) and inhibits infection of all influenza A, B viruses has not been found so far in nature, and the invention provides such a molecule for the first time in the world.

It is emphasized that an importance of the molecule is being rapidly increased at present as an high-impact molecule in that it can bind to both of HPAI viruses and new type of influenza viruses that have emerged due to variation of HPAI which is capable of transmitting

among humans, and that it can develop as an epoch-making anti-influenza drug that can inhibit infection of both the viruses.

That is, HPAI A virus (H5N1 strain) has transmitted directly from chicken to human in 1997 at Hong Kong. It was found that the virus was trasnfered directly from low pathogenic duck influenza virus (H5N1) to human via goose. At 1997, the virus transmitted and infected to human by recognizing an avian type receptor sugar chain (Neu5Acα2-3Galβ1-4(3)GlcNAc-) that an avian possesses and bound to the avian type receptor sugar chain that is expressed a little at the depth of human respiratory tract. However, the present inventor et al have found that a certain kind of strain (i.e. virus that was isolated from parent and child infected with H5N1 in 2003 at Hong Kong) has caused variation after 2003, and that it also binded to human type receptor sugar chain, i.e. Neu5Acα2-6Galβ1-4(3)GlcNAc- (Kyoko Shinya, Masato Hatta, Shinya Yamada, Ayato Takada, Shinji Watanabe, Peter Halfman, Taisuke Horimoto, Gabriele Neumann, Wilina Lim, Yi Guan, Malik Peiris, Makoto Kiso, Takashi Suzuki, Yasuo Suzuki, Yoshihiro Kawaoka: Characterization of a Human H5N1 Influenza A Virus Isolated in 2003. *J. Virol.*, 79, 9926-9932 (2005)). Also, the present inventor et al have found that HPAI that was isolated from sister who nursed her elder brother infected with HPAI virus in Vietnum has also caused variation to be capable of binding to a human type sialo sugar chain receptor (Neu5Acα2-6Galβ1-4(3)GlcNAc-) that exists in great amount at an upper portion of a human respiratory tract (Q.M. Le, M. Kiso, K. Someya,Y. T. Sakai, T. H. Nguyen, K. H. L.Nguyen, N. D. Pham, H. H.Ngyen, S. Yamada, Y. Muramoto, T. Horimoto, A. Takada, H. Goto, T. Suzuki, Y. Suzuki, & Y. Kawaoka: Isolation of drug-resistant H5N1 virus. *Nature*, 437, 1108 (2005)). That is, it has become evident from the researches by the inventor et al that the HPAI virus is being caused variation to be capable of transmitting to humans.

Actually, an infection of a HPAI virus to domestic fowls such as chicken is currently being spread in more than 45 countries, and an occurrence of a transmission threof to humans has been confirmed in 12 countries (WHO reports). The number of infectors with influenza A virus of H5N1 strain are 310 at June 5, 2007, and 189 of them were dead, and a death rate is near 61 %. As such, it has highly virulent nature (WHO reports). Moreover, infectors and dead persons are being increased without decrease. If the virus causes variation to be capable

of effectively binding to a human type receptor, an infection between humans to humans will become easy and a high risk of pandemic will be caused. Therefore, measures to cope with the situation are being made by WHO and many countries.

The novel molecule of the invention has a unique functional characteristic that those known in prior arts do not possess, that it includes both HPAI receptor (2-3) and human type receptor (2-6) within the same molecule, binds to all of avian influenza viruses and human influenza A, B viruses, and inhibits an infection of all the viruses.

Thus, the novel molecule of the invention has a possibility to develop as an infection inhibitor for a new type influenza virus that binds to 2-6 or both of 2-3 and 2-6, of which a possibility of outbreak is extremely apprehensive; as a very useful medicine; as a new diagnostic drug to check a variation of HPAI (receptor binding specificity: 2-3) to human type (receptor binding specificity: 2-6); and as a new material capable of specifically adsorbing and inhibiting a HPAI virus and a new type influenza virus capable of infecting among humans. I believe that an idea included in the molecule could become realized for the first time from my own studies so far and it has a high patentability over the prior art.

The sugar chain molecule of the invention was obtained from the inventor's (i.e. Yasuo Suzuki's) own studies, and the description in the specification is the first disclosure in the world. The molecule is that we have obtained from an allantoic membrane of embryonated hen eggs for the first time in the world, and will not be an impracticable concept. Accordingly, I believe that the molecule could not easily derive from influenza viruses or virus binding sugar chains of prior arts. Moreover, it was found from the inventor's own method and knowledge that the molecule binds to avian and the other animal influenza viruses and also binds to human influenza viruses, and inhibits infection thereof (stated otherwise, binds to all influenza A, B viruses and inhibits infection of all influenza A, B viruses). That is, the invention was made for the first time based on the inventor's own art, knowledge, and insight so far. It will be an invention of extremely high level that even a skilled artisan in this technical field will not be able to easily achieve. Accordingly, I believe that the claimed invention will not be obvious over the prior art.

8. I further declare that all statements, including the attached sheet, made herein of my own knowledge are true, and that all statements on information and belief are believed to be true;

and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

June 29, 2007 Yasuo Suzuki

Date **Declarant; Yasuo SUZUKI**

Academic Papers, Books Published, etc. of the Declarant

Academic Papers

Koji Matsuoka, Chiharu Takita, Tetsuo Koyama, Daisei Miyamoto, Sangchai Yingsakmongkon, Kazuya I.P.J. Hidari, Wipawee Jampangern, Takashi Suzuki, Yasuo Suzuki, Ken Hatano, and Daiyo Terunuma: Novel linear polymers bearing thiosialosides as pendant-type epitopes for influenza neuraminidase inhibitors.

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